

U.S. Department of Justice

United States Attorney Southern District of New York

The Silvio J. Mollo Building One St. Andrews Plaza New York, New York 10007

December 2, 2021

By ECF and Electronic Mail

The Honorable Kimba M. Wood United States District Judge Southern District of New York Daniel Patrick Moynihan United States Courthouse 500 Pearl Street New York, NY 10007

Re: <u>United States</u> v. <u>Fernando Serrano</u>, S1 16 Cr. 542 (KMW)

Dear Judge Wood:

The defendant, Fernando Serrano, is scheduled to be sentenced by this Court on December 9, 2021 at 10:30 a.m. In advance of sentencing, the Government respectfully submits this letter to advise the Court of the pertinent facts concerning the assistance that Serrano provided to the investigation and prosecution of other individuals, in particular with respect to Serrano's assistance in the investigation and prosecution of other individuals involved in Insys Therapeutics's payment of bribes to physicians in return for those physicians prescribing large volumes of the fentanyl narcotic Subsys.

For the reasons set forth more fully herein, and assuming that Serrano continues to comply with the terms of his cooperation agreement and commits no additional crimes before sentencing, the Government intends to move at sentencing, pursuant to Section 5K1.1 of the United States Sentencing Guidelines (the "Guidelines") and Title 18, United States Code, Section 3553(e), that the Court sentence Serrano without regard to any mandatory minimum and in light of the factors set forth in Section 5K1.1(a)(1)-(5) of the Guidelines.

I. Offense Conduct

As detailed in the Presentence Investigation Report ("PSR"), from October 2013 through June 2015, Serrano was a sales representative for Insys Therapeutics ("Insys") in the Manhattan sales territory. During his time at Insys, Serrano participated in the conspiracy to pay bribes and kickbacks to physicians in the form of speaker program fees in exchange for those physicians prescribing Insys's fentanyl-based drug, Subsys.

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A. Background on Subsys and the Insys Speakers Bureau

Fentanyl is a synthetic opioid approximately 50 to 100 times more potent than morphine. It is classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it has a high potential for abuse. (PSR \P 30).

In January 2012, the U.S. Food and Drug Administration (the "FDA") approved Subsys, a fentanyl spray administered sublingually (i.e., under the tongue), for the management of breakthrough pain in cancer patients who were already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. The Subsys label expressly warned against prescribing the drug to patients who were not already opioid tolerant, "[d]ue to the risk of fatal respiratory depression." In March 2012, Subsys entered the commercial market. (PSR ¶ 29).

Unlike some fentanyl-based medications, such as transdermal patches, Subsys is in a category of drugs known as Transmucosal Immediate Release Fentanyl ("TIRF") products, which are rapid-onset opioids designed to treat breakthrough pain in opioid-tolerant adults with cancer. Because of the risk of misuse, abuse, and addiction associated with TIRF products, including Subsys, practitioners must enroll in a mandated FDA program known as the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy program (the "TIRF REMS Program") and complete required training and testing in order to prescribe Subsys and other TIRF products for outpatient use. Patients, too, must enroll in the TIRF REMS Program in order to be prescribed TIRF products, including Subsys. (PSR ¶ 31).

In August 2012, Insys established the Insys Speakers Bureau, a roster of doctors and other health care providers paid purportedly to provide educational presentations, known as speaker programs, about Subsys. Rather than recruit potential speakers based on their qualifications as educators, Insys targeted speakers who would be willing to prescribe Subsys in large volumes. Insys executives instructed sales representatives to focus their time and resources on a few select doctors and provide them with lucrative speaker fees, among other benefits, in exchange for prescribing high quantities of Subsys. After the Speakers Bureau launched, Insys executives tracked and circulated statistics regarding speakers' prescribing habits. For a time, Insys calculated each speaker's "ROI"—return on investment—by dividing the sales generated from the practitioner's Subsys prescriptions by the amount Insys had paid that practitioner in speaker fees. (PSR ¶¶ 19, 46).

B. Serrano's Participation in the Conspiracy

1. Initial Hiring and Training at Insvs

Serrano was employed as a mortgage broker in the Summer of 2013 when he learned about a job opening at Insys. Serrano first learned about the employment opportunity after meeting Jonathan Roper at a birthday party of a mutual friend. Roper had just been promoted to a supervisory position at Insys and told Serrano the company was looking for a new sales

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representative to fill his prior role. (Tr. 558). Poper advised Serrano that Serrano could make a lucrative bonus if he decided to work for Insys. (*Id.*). Serrano sent his resume to Roper and was quickly offered a job as a sales representative for the Manhattan sales territory after a brief telephone interview with Sunrise Lee, a Regional Sales Director at Insys. (Tr. 559-60). Serrano had never previously worked in pharmaceutical sales, but no concerns in this regard were raised during his interview. (*Id.*).

In September 2013, Serrano attended new employee training at Insys's headquarters in Chandler, Arizona. At the training, Alec Burlakoff,³ the Insys Vice President of Sales, instructed the new sales representatives to identify large prescribers and "live in their doctors' offices," meaning the sales representatives should spend a large portion of their time at these select doctors' offices. (Tr. 563). Serrano quickly came to understand that Insys's sales strategy was to target a few doctors that were large prescribers of Subsys and to focus his efforts predominantly on these few doctors.

Serrano was provided with an iPad containing a call list of doctors in Manhattan at the end of the training. There were no oncologists on the list provided by Insys, despite the fact Subsys was only approved by the FDA for treatment of breakthrough cancer pain. Serrano's sales list consisted primarily of pain management doctors. (Tr. 565).

2. Serrano's Initial Time in the Field

Serrano formally began his employment on October 1, 2013. At that time, Serrano was the only sales representative assigned to the Manhattan sales territory and was taking over Roper's list of doctors now that Roper had been promoted to District Sales Manager. Roper advised Serrano that Serrano's most important doctors would be Dr. Gordon Freedman and Dr. Jeffrey Goldstein, both of whom were speakers for the company. (Tr. 566).

Roper invited Serrano to attend a dinner with Freedman in late September 2013 prior to Serrano's formal start date in order to introduce Serrano to Freedman. The dinner consisted of just Roper, Freedman, and Serrano, and was a purely social dinner during which they watched the New York Rangers hockey game on television. Serrano realized that the dinner was actually a purported speaker program only when Roper asked Serrano to sign a sign-in sheet for the program after the fact. (Tr. at 567-69).

Serrano began to organize speaker programs for both Freedman and Goldstein, and these programs were predominantly social affairs where little in the way of education about Subsys occurred. (*E.g.*, Tr. 572-74, 577). While Freedman and Goldstein were supposed to conduct a

¹ "Tr." refers to the transcript of the trial of Dr. Gordon Freedman in *United States v. Gordon Freedman*, 18 Cr. 217 (KMW).

² Lee was convicted at trial in the District of Massachusetts. *See United States v. Babich et al.*, 16-cr-10343-ADB (D. Mass.).

³ Burlakoff pleaded guilty in the District of Massachusetts and testified as a cooperating witness for the Government at trial. *See United States v. Babich et al.*, 16-cr-10343-ADB (D. Mass.).

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slide presentation at the speaker programs, this rarely, if ever, occurred. The audience for the speaker programs rarely consisted of other doctors seeking to be educated about Subsys.

3. Forging Sign-in Sheets

Serrano began forging sign-in sheets for Insys speaker programs early in his tenure at Insys. Forging sign-in sheets for the speaker programs was necessary to make the dinners appear to have had a legitimate audience of peer-level physicians. Per Insys policy, at least two healthcare professionals in addition to the Speaker needed to be in attendance. But often there were not two other healthcare professionals present, and thus Serrano would have to add the name and signature of a healthcare professional who was not actually there. In addition, there was a \$125 spending limit per attendee, but at times this limit was exceeded. Accordingly, Serrano would add additional purported attendees to the sign-in sheets in order to ensure that the spending per attendee was within the \$125 limit. (Tr. 607-08). Serrano learned the mechanics for forging the sign-in sheets in this manner from Roper. (Tr. 608).

At times, Serrano would ask doctors to sign a sign-in sheet for a program they had not attended. On other occasions, Serrano added the names and signatures of doctors and other healthcare professionals to sign-in sheets without their permission. (*E.g.*, Tr. 58-81).

4. Serrano's Understanding That the Speaker Program Fees Were in Exchange for Large Volumes of Prescriptions

Serrano quickly came to understand that the purpose of the sham speaker programs he was organizing was not to educate other physicians but rather to cause the doctors receiving the lucrative speaker program fees to prescribe large volumes of Subsys. (Tr. 574-75). Indeed, this message – that the speaker program fees were provided to the doctors with the expectation they would prescribe large volumes of Subsys in return – was delivered to Serrano on numerous occasions during his time at Insys. By way of example, in a November 14, 2013 email from Roper to Serrano and the other sales representatives Roper supervised, Roper stated in relevant part:

Furthermore, the lack of new RXs is going to bury us and nothing has changed. Unfortunately for many reps, it's going to to [sic] be a sad holiday season and it's out of my control at this point. DONT BE ONE OF THOSE REPS! Almost all of you have speakers, use that to your advantage and repeatedly inform them of one simple guideline for them to follow as Insys speakers, NO SCRIPTS, NO PROGRAMS.

(GX 1384).⁴ This message was reinforced with Serrano time and time again, both orally and in writing, during his employment at Insys. (Tr. at 576-77).

5. Serrano's Time at Offices of Speaker Physicians

⁴ "GX" refers to Government Exhibits offered at the trial of Gordon Freedman in *United States v. Freedman*, 18 Cr. 217 (KMW).

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Consistent with the guidance Serrano had received from Roper, Burlakoff, and other members of Insys management, Serrano devoted the vast majority of his time to the doctors that were Insys speakers. Serrano would regularly bring lunch to Freedman's and Goldstein's offices, and later, after she became a speaker, to Voudouris's office.⁵ At one point during his tenure, Serrano was visiting Freedman's and Voudouris's offices three to four times per week. (Tr. 599).

Insys played an active role in attempting to secure insurance coverage for prescriptions of Subsys written by the physicians. Serrano worked with Freedman's office staff to submit paperwork to a division of Insys called the Insys Reimbursement Center (IRC), which used that information to interact with the insurance companies to obtain insurance coverage for the prescription. (Tr. 592). The forms submitted to the IRC, called "opt-in" forms, provided information about the patient's diagnosis and other medical conditions. (Tr. 592). Serrano worked with Freedman's office staff to complete opt-in forms, which included Serrano having access to patient medical records. At times, Serrano added false diagnoses to the opt-in forms in order to ensure that the insurance company approved the prescription. (Tr. 594-95).

6. Serrano's Interactions with the Insys Speakers

Serrano had substantial interactions with four of the five doctors indicted in *United States* v. *Freedman et al.*, 18 Cr. 217 (KMW). Serrano provided the Government with substantive and incriminating information about each of the four doctors.

a. Gordon Freedman

Serrano was Freedman's assigned sales representative during the entirety of Serrano's tenure at Insys from October 2013 through June 2015. Serrano had extensive interactions with Freedman during this period, the details of which Serrano testified about at length during Freedman's trial.

Serrano organized speaker programs where Freedman was the designated speaker typically on a weekly basis. These were frequently sham programs where no education about Subsys occurred. Frequently, there were not even other physicians present at the programs for Freedman to educate. Many of the physicians and other healthcare professionals who did attend came to Freedman's programs on a repeated basis, and thus did not need to be educated about

⁵ Insys paid for the lunches. In order to justify the lunches, Serrano would have the doctors and their medical staff complete sign-in sheets for purported "lunch and learn" events. In reality, there was no education about Subsys that occurred at these lunches. (Tr. at 599-603).

⁶ The IRC frequently provided false and misleading information to insurance companies about patient diagnoses in order to obtain insurance coverage for Subsys prescriptions. Certain Insys executives were charged in *United States v. Babich et al.*, 16-cr-10343-ADB (D. Mass.), for their role in the scheme to defraud insurers through the IRC. The Government is not aware of any evidence to suggest that Serrano knew the IRC was providing false information to insurers.

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Subsys. On other occasions, Serrano invited women he was dating and others who were not in the healthcare field to attend the programs.

During his testimony at Freedman's trial, Serrano recounted in detail numerous sham programs that he organized for Freedman. (*E.g.*, Tr. 567-69, 663-64, 677-82, 683-85, 686-89, 693-96). As is discussed above, Serrano frequently needed to add the names and signatures of healthcare professionals who had not been present at the speaker programs to sign-in sheets in order to make it appear that the programs had a legitimate audience. Serrano discussed with Freedman on a few occasions the fact that Serrano needed to obtain signatures for the sign-in sheets before he could submit the paperwork to Insys. Freedman instructed Serrano to obtain signatures from Freedman's office staff and fellow doctors in his private practice, and Serrano did so on at least a few occasions. (Tr. 612-16).

In 2014, after Insys learned that it was under investigation, the company instituted a purported compliance monitoring program for its speaker programs under which auditors would attend speaker programs to ensure they were educational and otherwise compliant with Insys policies. In reality, the sales representatives organizing the speaker programs were warned in advance by company management that an auditor would be attending the speaker program. For these programs, Serrano would ensure that there was an audience of peer-level physicians in attendance. Serrano also spoke with Freedman about the fact that Freedman needed to conduct the entire slide presentation in light of the auditor's attendance, and Freedman did so. (Tr. 704-11). Serrano testified that the occasions when the auditor was present were the only times he saw Freedman actually conduct the slide presentation regarding Subsys. (Tr. 711).

In early 2014, Insys management instructed Serrano that they were going to guarantee Freedman speaker programs every week for the entire year. Serrano understood that the purpose of guaranteeing speaker programs to the doctors in advance was to show the speakers Insys was committed to paying them for the coming year, with the expectation the doctors would prescribe more Subsys in return. (Tr. 640-43). Serrano spoke to Freedman about the fact Insys had committed to provide him with speaker programs every week in the coming year, and Freedman was pleased. (Tr. 643).

Serrano observed that Freedman's prescribing of Subsys had increased substantially in 2014 from 2013. (Tr. 740). By the end of 2014, Freedman was the fourth largest prescriber of Subsys in the country. (Tr. 740). He was also paid more by Insys than any other doctor in the nation in 2014. Serrano was under significant pressure to ensure that Freedman generated large volumes of Subsys prescriptions. Text messages recovered from Serrano's phone (which Serrano consented to have searched in connection with his cooperation) showed that Roper frequently sent messages to Serrano putting pressure on him to generate prescriptions from Freedman and Voudouris, who were Serrano's two assigned physicians that were speakers for Insys. (*See, e.g.,* GX 532, Tr. 753-54). Serrano had conversations with Freedman regarding the volume of his Subsys prescriptions. Serrano testified that on multiple occasions he told Freedman in substance that "[Insys] management was giving me a lot of pressure in regards to the new patients. So I would tell him that if he can help me out by opting-in a few patients, that would be great," and that Freedman responded by saying, "I'll see what I can do." (Tr. 755).

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In late March 2015 and early April 2015, Insys ran a sales promotion contest known as the "opt-in contest." This contest provided an incentive-based bonus to Insys sales representatives who could get the most new patients prescribed Subsys. (Tr. 764-65; GX 1431). During the contest, Serrano spoke with Freedman and informed him about the opt-in contest. (Tr. 768-69). Serrano informed Freedman in substance that Insys had a contest and that the sales representative that could get the most opt-ins would win a bonus. (Tr. 768-69). Serrano asked Freedman if he could help Serrano out. Freedman responded that he would "see what I could do." (Tr. 769). Thereafter, Freedman did "opt in" new patients by prescribing Subsys. While Freedman had only seen fit to prescribe Subsys to three new patients between November 2014 through March 2015 (GX 16), a period of five months, he prescribed Subsys to the same number of new patients—three—in the eight days between March 31, 2015 through April 7, 2015, which coincided with the opt-in contest. (Tr. 776; GX 1462, GX 1463, GX 1465, GX 519). As to one of these new patients, Freedman caused an opt-in form to be prepared and submitted the day before she even went in for her April 1, 2015 appointment with Freedman, as Serrano testified and as was corroborated by contemporaneous emails with the Insys Reimbursement Center and text messages between Serrano and Freedman. (GX 1462; GX 519; Tr. 769-74).8

b. Jeffrey Goldstein

When Serrano first began at Insys on October 1, 2013, he was the assigned sales representative for Goldstein and Dr. Todd Schlifstein. Goldstein and Schlifstein were cofounders of Fountain Medical Group, a private medical practice on the Upper East Side. The practice included a pain management component, as well as a medical spa. At the time Serrano started, Goldstein was already a speaker for Insys. Serrano organized speaker programs for Goldstein. These programs involved no education about Subsys and Goldstein did not use the preapproved slide deck. Serrano described these programs as purely social gatherings. Serrano recalled that Goldstein invited individuals to speaker programs who were not in the healthcare field. In one instance, Goldstein had his accountant attend a speaker program. Given that the accountant was not in the healthcare field, he was not allowed to be present at the speaker program per Insys rules. Serrano forged the sign-in sheet by putting down the name of another physician who had not been at the speaker program.

Goldstein and Serrano quickly clashed, leading Goldstein to demand that Insys assign him a new sales representative. Even after Serrano no longer was Goldstein's assigned sales representative, Serrano periodically attended speaker programs led by Goldstein. These programs were social in nature and frequently involved excessive alcohol and drug use by certain of the attendees. On certain occasions, Serrano used cocaine while at speaker programs, including Goldstein's speaker programs. In particular, Serrano recalled an instance when he and Goldstein took turns using cocaine in the restaurant bathroom during a speaker program. (18 Cr.

⁷ Freedman admitted during his testimony that Serrano had told him about the opt-in contest (Tr. 1595) but claimed that he did not care whether Serrano won the contest and merely told him that "if I have appropriate patients, I'll put them on the drug." (Tr. 1595).

⁸ Serrano further testified that this was not the only time Freedman had told Serrano in advance of a patient's visit that Freedman was planning to prescribe the patient Subsys. (Tr. 774).

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217 Indictment ¶ 39(a)). Serrano also used marijuana with Goldstein and other Insys employees prior to Goldstein's speaker programs on certain occasions. (18 Cr. 217 Indictment ¶ 39(a)).

Serrano also disclosed that Goldstein accepted other items of value from Insys. In particular, Serrano was present for a conversation between Roper and Goldstein regarding Insys paying for Fountain Medical Group's holiday party at a restaurant on the Upper East Side.⁹

c. Todd Schlifstein

When he began working at Insys, Serrano was also the assigned sales representative for Schlifstein, Goldstein's co-partner at Fountain Medical Group. At that time, Schlifstein had prescribed some Subsys but not large volumes. Soon after Serrano began working in the field, Serrano discussed with Roper the possibility of recruiting Schlifstein as a speaker in order to increase his prescriptions. Serrano spoke to Schlifstein about the possibility of becoming a speaker for Insys, and Schlifstein expressed interest.

Sunrise Lee, the Regional Sales Director, travelled to Manhattan in late October 2013 to meet Schlifstein and "vet" him as a possible Insys speaker. During Lee's visit, Serrano organized a speaker program where Goldstein was the designated speaker. Also present were Roper, Lee, and Schlifstein, among others. No education occurred at the speaker program, which was a purely social dinner. After the dinner, the group went to Sapphire, a strip club on the Upper East Side. When they got to Sapphire, Lee put down her credit card to book a private room. In the private room, there was bottle service and Schlifstein and Goldstein both received multiple private lap dances. The bill for the evening was \$4,100. 10 (PSR ¶ 83).

Following Lee's visit to New York, Lee informed Serrano that Lee had had a conversation with Schlifstein and that Schlifstein would be providing Serrano with a list of patients Schlifstein planned to prescribe Subsys to. (PSR ¶ 84). Soon thereafter, Serrano and Schlifstein met in Schlifstein's office. During the meeting, Schlifstein reviewed his calendar of upcoming appointments and identified specific patients for whom he said he would prescribe Subsys. Serrano wrote down these patients' names and the dates of their scheduled appointments. (PSR ¶ 84).

On November 18, 2013, Insys nominated Schlifstein as a speaker. Schlifstein's Subsys prescriptions rose dramatically thereafter. Serrano, however, was soon removed as Schlifstein's assigned sales representative as Insys brought in a new sales representative for both Goldstein and Schlifstein after Goldstein informed the company he no longer wanted Serrano to be his assigned sales representative.

⁹ Serrano's account was corroborated by emails and receipts produced by the restaurant. Serrano was unaware of these records at the time he informed the Government during a proffer session that Insys had paid for Fountain Medical Group's holiday party.

¹⁰ Serrano disclosed during the proffers other occasions when he took doctors to Sapphire while employed at Insys.

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d. Dialecti Voudouris

After Goldstein caused Serrano to be removed as his assigned sales representative, Serrano sought to identify a new speaker who could prescribe large volumes of Subsys. In the beginning of 2014, Serrano identified another pain management physician as a speaker and nominated this doctor to become a speaker for the company. This doctor conducted a handful of speaker programs for Insys, during which he presented the entirety of the slide deck presentation. (Tr. 714). However, this physician's prescribing of Subsys did not increase even after he was allocated speaker programs. Eventually, Serrano and Roper met in-person with this doctor to tell him that they expected him to prescribe more Subsys. (Tr.714-15). The doctor refused to agree to prescribe Subsys to more patients, and his prescriptions of Subsys remained constant. Accordingly, soon thereafter, Serrano was instructed by Insys management to cease scheduling speaker programs for the physician. (Tr. 715-16).

Serrano did eventually recruit another speaker for Insys, Dialecti Voudouris, an oncologist. Serrano first learned of Voudouris from a friend who was a sales representative for another pharmaceutical company. Serrano was particularly interested in recruiting Voudouris as a speaker because she was an oncologist and therefore had cancer patients. Around this time in mid-2014, Insys management had instructed the salesforce to seek to identify more oncologists to prescribe Subsys because Insys had recently been criticized in the press regarding the fact that the vast majority of Subsys prescriptions were off-label and written by pain management doctors rather than oncologists. (Tr. 746).

Serrano first met Voudouris by inviting her and another doctor Voudouris was friends with to one of Freedman's speaker programs. Soon after, Serrano met with Voudouris at her office and discussed with her the possibility of becoming a speaker for Insys. Voudouris said she was interested. Roper submitted a nomination for Voudouris to become a speaker in or about August 2014. (18 Cr. 217 Indictment, ¶ 113). Insys allocated a substantial number of speaker programs to Voudouris for the third quarter of 2014.

After Voudouris became an Insys speaker, Serrano learned that several Insys executives, including Burlakoff, were planning to come to New York City in order to meet with Voudouris. Serrano was told in advance that Burlakoff planned to speak with Voudouris about the fact that Insys was expecting her to prescribe more Subsys now that she was an Insys speaker. Serrano had not personally ever been present at such a conversation between Burlakoff and a doctor, but had heard about such conversations from others at the company, including Roper. Serrano testified that these meetings between Insys executives and a doctor where the Insys executives explicitly told the doctor they were expected to prescribe more Subsys in return for the speaker program fees was known within the company as "the conversation." (Tr. 748-49). On September 2, 2014, Serrano attended a dinner at a high-end restaurant in Manhattan with Voudouris, Burlakoff, Roper, and several other Insys executives who had travelled to New York for the occasion. (18 Cr. 217 Indictment, ¶ 114). During the dinner, Burlakoff told Voudouris, in

¹¹ Jeffrey Pearlman, another Insys manager, also testified at Freedman's trial about the meaning of the term "the Conversation," and recounted a similar dinner meeting between Burlakoff and Freedman that occurred in early 2013. (Tr. 137).

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substance and in part, that he wanted her to prescribe Subsys to one new patient every day, and that Voudouris would be allocated Speaker Programs if she continued prescribing Subsys. (*Id.*; Tr. 749).

After the September 2, 2014 dinner, Burlakoff and Roper informed Serrano that they were not satisfied with Voudouris's Subsys prescriptions. In particular, on or about September 9, 2014, Burlakoff forwarded an email with recent Subsys prescription data to Serrano, Roper, and two of the executives who had attended the September 2 dinner with Voudouris and wrote in relevant part, "No scripts from Dr. Viduores [sic], unacceptable for ALL of us?????? UNACCEPTABLE." Roper sent a reply all message to the email that same day, instructing Serrano to "set up a meeting for me asap with Dr. Voudouris after work hours" and noting that the company had "invested way too much at this point to only have a 'few' pts [patients] on Subsys." Roper added, "1 NEW PT A DAY is what was agreed upon. Get it done and remember, DON[']T LET THE DR. SELL YOU, YOU SELL THE DOCTER [sic]!!" Serrano responded later that day stating that he would "handle this issue this evening with her before her speaker training" and that "[t]he message WILL be delivered." (18 Cr. 217 Indictment, ¶ 116).

Serrano and Roper ultimately met with Voudouris in person at her office. They informed Voudouris that Insys expected Voudouris to write more prescriptions and that if she prescribed more Subsys Insys would nominate her to become a national speaker, which would mean a higher honorarium. (18 Cr. 217 Indictment, ¶ 117; Tr. 750). Following this discussion, Voudouris's prescriptions of Subsys rose substantially. (18 Cr. 217 Indictment, ¶ 118, Tr. 750). By the end of the first quarter of 2015, Voudouris was approximately the 10th-highest prescriber of Subsys nationally. (18 Cr. 217 Indictment, ¶ 120).

Voudouris's speaker programs were also predominantly social in nature. Serrano frequently forged sign-in sheets for her speaker programs, either by adding the names of healthcare professionals who agreed to sign sign-in sheets for programs they had not attended, or by adding the names and signatures of healthcare professionals without their permission. At times, Voudouris would add the names of physicians she knew to sign-in sheets herself, or would give Serrano names that he should add to the sign-in sheets. All of this was done to make the programs appear legitimate, educational events, when in truth and fact they were not. (18 Cr. 217 Indictment, ¶ 36(d)).

Serrano provided information that Voudouris also wrote refill prescriptions of Subsys that she knew were unnecessary for patients who already had an ample supply of Subsys based on prior prescriptions written by Voudouris. Voudouris wrote these refill prescriptions in order to continue prescribing high volumes of Subsys. (18 Cr. 217 Indictment, ¶ 122). In order to fill prescriptions unnecessarily, Voudouris often sent Subsys prescriptions to a pharmacy in Manhattan ("Pharmacy-1") where she was friendly with the owner and the head pharmacist. Voudouris then directed Serrano to retrieve the Subsys from Pharmacy-1 and deliver it to her at her private medical office. Rather than provide the Subsys to the patients listed on the prescriptions Voudouris had unnecessarily written, Voudouris instead stockpiled boxes of the Fentanyl Spray in her office at medical office. (18 Cr. 217 Indictment, ¶ 123)

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Serrano also sought out Voudouris's assistance in connection with the "opt-in" contest described above. Serrano asked Voudouris to assist him by prescribing Subsys to new patients. Voudouris gave Serrano and another Insys employee access to patients names and other patient information that Serrano and the other Insys employee then used to complete opt-in forms for these patients. (18 Cr. 217 Indictment, ¶ 126). Many of the patients listed on the forms had not authorized Voudouris to share their medical information with Insys in order to help Serrano win a contest. As a result, Voudouris's office submitted opt-in forms for approximately 26 patients during a short period in or about early April 2015. (18 Cr. 217 Indictment, ¶ 126). In reality, Voudouris did not intend to prescribe Subsys to the vast majority of the patients whose information she disclosed to Serrano and Insys in or about early April 2015 for the purpose of helping Serrano complete and submit opt-in forms. (18 Cr. 217 Indictment, ¶ 127). Indeed, many of the patients listed on opt-in forms that Voudouris's office submitted to Insys were unaware that opt-in forms had been submitted on their behalf and that prior authorization for Subsys was being sought from their insurer. When patients began to receive phone calls from their insurers regarding prior authorization for Subsys, some patients called Voudouris's office to complain. On or about April 14, 2015, Voudouris sent Serrano a text message stating, "Patients are already calling me to complain that they are getting calls at home!!!" Voudouris further stated, "Did you win? (It would be worth it then!)." (18 Cr. 217 Indictment, ¶ 128).

7. Serrano's Compensation at Insys

Serrano received an annual base salary of approximately \$40,000 during his time at Insys. Serrano was predominantly compensated in sales commissions, which were quite large given that certain of the doctors assigned to Serrano were some of the largest prescribers of Subsys in the country. The Government estimates based on its review of internal Insys records that Serrano received approximately \$522,462 in bonus payments during his employment at Insys. 12

8. Serrano's Termination from Insys

In June 2015, Serrano received an email from Insys's Compliance Department informing him that he would not be permitted to organize any Speaker Programs for the third quarter of 2015. The letter stated that this was due to Serrano having too many "repeat attendees" at his Speaker Programs. A few days after he received the letter from Compliance, Serrano received a phone call notifying him he had been terminated effective immediately. Serrano went to Freedman's office and told him he was fired due to the repeat attendee issue.

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¹² Serrano admitted to the forfeiture allegations in the Superseding Information at the time he pled guilty, and agreed to forfeit all property, real and person, which constitutes, or is derived from, proceeds traceable to the commission of said offenses, including but not limited to a sum of money in United States currency representing the amount of proceeds traceable to the commission of the offenses charged in Counts One, Two, and Six of the Information. The Government is submitting a consent preliminary order of forfeiture/money judgment along with this submission in the amount of \$522,462, which represents Serrano's sales commissions.

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Shortly after Serrano was fired, a long-form investigative piece was published online by the Southern Investigative Reporting Foundation about Dr. Freedman, the large Speaker Program fees he was receiving from Insys, and his large number of Subsys prescriptions. ¹³ Serrano was quoted in the SIRF article as saying that he felt Insys had unlawfully terminated him and that he planned to sue Insys. While Insys initially withheld Serrano's bonus payment, the company eventually paid Serrano his bonus and Serrano never filed an action against Insys.

II. Miscellaneous Other Criminal and Bad Acts

In addition to the above crimes during his employment at Insys, Serrano disclosed to the Government the following additional criminal conduct and other bad acts during his proffers:



Failure to Report Rental Income and Stock Sale Proceeds. Serrano disclosed to the Government certain income that he did not report on his taxes. In particular, Serrano owned a single family residence with two friends located in Long Island, which he and the two friends purchased in 2008. Serrano lived in the home until 2010 and then began renting out the property. Serrano estimated that between 2010 and 2016 when he began proffering with the Government that he had personally earned approximately \$40,000 in rental income from the property. Serrano did not report this rental income on his state or federal returns. As of the time of Serrano's plea, there were tenants occupying the property but these tenants had ceased paying rent and Serrano was contemplating eviction proceedings. In addition, Serrano exercised certain stock options in Insys stock in 2015 following his termination, which generated between approximately \$20,000 and \$30,000 in proceeds. Serrano did not report this income on his tax

¹³ The article is available at https://ffj-online.org/2015/07/14/the-darkening-world-of-insystherapeutics/ (last visited on Aug. 4, 2021).

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returns. Serrano's cooperation agreement provides that he will file accurate amended tax returns for tax years 2010 through 2015 and will pay, or will enter into an agreement to pay, past taxes due and owing by him to the Internal Revenue Service and any appropriate state tax authorities on such terms and conditions as are agreed upon between him and the IRS and the state tax authorities.¹⁴

False Statements to Lenders. Serrano disclosed to the Government that while he was employed in the mortgage industry as a loan officer between in or about July 2006 and June 2008 he, at times, submitted inflated income information to lenders in connection with his clients obtaining mortgages. This inflated income information was provided in connection with "no documentation" loans, meaning that the lender banks knew that the information had not been verified independently and the banks did not demand to see documentation of income and liabilities. Such loans were prevalent during the time period that Serrano worked in the mortgage industry.

Reporting Inflated Income on Credit Card Applications. Serrano disclosed to the Government that between in or about 2007 through in or about 2014, on a few occasions he reported inflated income when applying for a credit card in order to obtain a higher spending limit.



False Information on Job Resumes. Serrano disclosed to the Government that he provided false information regarding his educational background on his resume when applying for employment between in or about 2012 through in or about 2016 when he began proffering with the Government. In particular, Serrano falsely claimed on his resume that he had graduated college, when in fact he was still a few credits short of graduation.

Driving an Uninsured Vehicle. Serrano disclosed to the Government that he drove an uninsured vehicle in or about 2016. Serrano was still driving this vehicle at the time of his first proffer session with the Government. Immediately after disclosing the issue in a proffer session, he obtained insurance for the vehicle with the assistance of his defense counsel.

¹⁴ Defense counsel reports that Serrano retained an accountant who, in or about February 2020, submitted an offer and compromise to the IRS for the relevant tax years. The offer and compromise has been pending since that time. Serrano recently received a letter from the IRS informing him that they will advise him as to their decision with respect to the offer and compromise in or about October 2021.

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Other Miscellaneous Bad Acts. Serrano disclosed other miscellaneous bad acts he had engaged in during his life. He disclosed that when he was approximately 18, he shoplifted a pair of baseball cleats. In his early 20s, he paid for drinks at a nightclub using a credit card he knew was over its spending limit and then left the nightclub without paying the bill.

III. Procedural History

Serrano and Roper were arrested on June 9, 2016 and charged by Complaint with conspiring to violate the Anti-Kickback Statute and violation of the Anti-Kickback Statute. ¹⁵ Serrano was released on his own recognizance that same day. Serrano and Roper were subsequently indicted on August 9, 2016 and charged with conspiring to violate the Anti-Kickback Statute, violation of the Anti-Kickback Statute.

In the Fall of 2016, Serrano, through his attorney, expressed an interest in cooperation. Serrano first proffered with the Government in November 2016, and had proffer sessions with the Government on approximately seven occasions prior to being offered a cooperation plea agreement. In connection with his efforts to cooperate, Serrano also provided consent to search his cellular phone, and produced hard copy records to the Government voluntarily. On or about May 30, 2017, Serrano pleaded guilty to superseding information S1 16 Cr. 652, which charged Serrano in six counts with (i) conspiring to violate the Anti-Kickback Statute, (ii) violating the Anti-Kickback Statute, (iii) knowingly and without authorization obtaining protected individually identifiable health information in violation of the Health Insurance Portability and Accountability Act (HIPAA), (iv) conspiring to commit honest services wire fraud, (v) aggravated identity theft, and (vi) health care fraud. 16 At the time of his plea, Serrano's bail was modified and he was released on a \$75,000 personal recognizance bond co-signed by two financially responsible persons and secured by real property. Serrano's conditions also included drug testing and treatment as directed by pretrial services and that he should participate in an outpatient drug treatment program approved by the pretrial services officer. Pretrial services reports there have been no issues with Serrano's compliance while on release.

On June 1, 2017, the Government filed Superseding Indictment S2 16 Cr. 652, which charged Roper with (i) conspiracy to violate the Anti-Kickback Statute, (ii) violation of the Anti-Kickback Statute, (iii) conspiring to commit honest services wire fraud, and (iv) aggravated identity theft. The Government relied in part on information and evidence provided by Serrano in bringing these superseding charges. Roper subsequently decided to cooperate with the

¹⁵ On the day of his arrest, Serrano spoke voluntarily with the FBI. During that interview Serrano was not completely truthful; he falsely claimed the speaker programs were educational. (Tr. 578-79).

¹⁶ The Government agrees with the Guidelines calculation set forth in the Presentence Investigation Report. Per the PSR, the total offense level is 26, and the defendant is in Criminal History Category II. (PSR ¶¶ 107-126). Accordingly, the applicable Guidelines range is 70 to 87 months' imprisonment, with a mandatory consecutive 24 months' imprisonment on the Aggravated Identity Theft count (Count 5). (PSR ¶ 157).

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Government and ultimately pled guilty, pursuant to a cooperation agreement, to Superseding Information S3 16 Cr. 542 on August 18, 2017.

In March 2018, the Government indicted Freedman, Goldstein, Schlifstein, Voudouris, and Alexandru Burducea in 18 Cr. 217 (KMW), charging all five defendants with conspiring to violate the Anti-Kickback Statute, violating the Anti-Kickback Statute, and conspiring to commit honest services wire fraud. Certain of the defendant doctors were charged with aggravated identity theft, and certain were charged with violating HIPAA. Burducea was also charged with making false statements to federal officials. Information and evidence provided by Serrano was in part relied on in filing these charges against the five defendant doctors. Goldstein, Schlifstein, Voudouris, and Burducea each pleaded guilty to one count of conspiring to violate the Anti-Kickback Statute before this Court. This Court sentenced Goldstein to 57 months' imprisonment, Schlifstein to 24 months' imprisonment, Voudouris to time served, and Burducea to 57 months' imprisonment, and ordered Goldstein to forfeit \$196,000, Schlifstein to forfeit \$127,100, Voudouris to forfeit \$119,400, and Burducea to forfeit \$68,400. Freedman proceeded to trial in this Court in November 2019. Serrano testified over the course of three trial days, which included lengthy cross-examination. The jury found Freedman guilty of conspiring to violate the Anti-Kickback Statute, violating the Anti-Kickback Statute, and conspiring to commit honest services wire fraud. Freedman was sentenced by this Court to 121 months' imprisonment in the 18 Cr. 217 case and was ordered to forfeit \$308,600.

IV. Serrano's Cooperation and Application of the Section 5K1.1 Factors

Section 5K1.1 of the Guidelines sets forth five non-exclusive factors that sentencing courts are encouraged to consider in determining the appropriate sentencing reduction for a defendant who has rendered substantial assistance. See U.S.S.G. § 5K1.1(a).

In sum, Serrano complied fully with the requirements of his cooperation agreement. He provided substantial and valuable assistance to the Government in connection with its investigation and prosecution of the bribery scheme involving Insys and doctors who accepted bribes from the company in return for prescribing a dangerous and potent opioid containing fentanyl. Serrano met with the Government numerous times for multiple hours per session in order to prepare for his trial testimony. He testified over the course of three trial days, which was substantially longer than any other witness at Freedman's trial. He was consistently truthful and forthcoming. He provided evidence and information that was new to the Government at the time he provided it and allowed the Government to successfully bring charges against four doctors that took bribes from Insys, as well as providing information and evidence that allowed the Government to bring superseding charges against Jonathan Roper, his former manager.

A. Timeliness of Assistance (U.S.S.G. § 5K1.1(a)(5))

Serrano's cooperation was timely. Serrano began cooperating soon after he was charged. He was charged by complaint in June 2016, was indicted in August 2016, and had his first proffer session with the Government on November 1, 2016. Serrano provided information and additional evidence in a timely fashion that allowed the Government to bring charges against others individuals involved in the Insys bribery scheme.

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B. <u>Truthfulness, Completeness, and Reliability of Serrano's Information</u> (U.S.S.G. § 5K1.1(a)(2))

With regard to the "truthfulness, completeness, and reliability" of the defendant's information, see U.S.S.G. § 5K1.1(a)(2), over the course of his many meetings with the Government and the FBI agents prior to his being signed up as a cooperating witness and in preparing to testify at Freedman's trial, Serrano was forthcoming and truthful about his own criminal conduct and that of other individuals. The fact that Serrano was forthcoming and truthful is demonstrated by, among other things, independent corroboration of certain information he provided to the Government. In addition, Serrano's disclosure to the Government of a host of additional criminal conduct – including conduct that the Government was not previously aware of – demonstrates he was being truthful, complete, and reliable. These additional crimes that Serrano disclosed included serious criminal conduct. By way of example, and as is described above, Serrano voluntarily disclosed to the Government during his proffer sessions that he, on a few occasions, added checkmarks to opt-in forms to indicate medical diagnoses that the patient did not actually suffer from in order to ensure that the insurance company covered the patient's Subsys prescription. The Government was not previously aware that Serrano had engaged in this conduct, and Serrano ultimately pled guilty to the crime of health care fraud as a result of this conduct.

While individuals seeking to cooperate all too frequently minimize their conduct in their initial proffers with the Government, Serrano never did so. Instead, he took full responsibility for his significant role in the crimes from the outset of his meetings with the Government, and he went further by telling the Government about substantial additional criminal conduct that he had engaged in with numerous other individuals.

C. Nature and Extent of Assistance (U.S.S.G. § 5K1.1(a)(3))

Serrano's cooperation was extensive by any measure. He spent hour after hour meeting with the Government in order to prepare for his trial testimony. This included meeting with the Government late into the evening after he was done with his workday and meeting on weekends. Serrano testified over the course of three trial days, which included lengthy cross-examination. His testimony lasted far longer than that of any other witness at trial.

Serrano also provided the Government with consent to search his cellphone, which yielded incriminating evidence against his manager Jonathan Roper, as well as against certain of the doctors that were ultimately indicted. By way of example, in an April 14, 2015 series of text message recovered from Serrano's phone, Serrano, Voudouris and another Insys employee referenced Voudouris's efforts to assist Serrano win the "opt-in contest" by completing opt-in forms for patients who had no idea opt-in forms were being submitted on their behalf or that prior authorization was being sought from their insurer. During this text message exchange, Voudouris stated "[p]atients are already calling me to complain that they are getting calls at home!!!" and added "Did you win? (It would be worth it then!). These messages were discussed in the Indictment. (*See* 18 Cr. 217 Indictment ¶ 128). Serrano's phone also contained hundreds of pages of incriminating text messages between himself and Roper dating back to as early as

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December 2014. These text messages were produced to Roper in discovery on or about March 1, 2017, and a superseding Indictment adding new charges against Roper was filed on June 1, 2017. Roper began proffering with the Government in July 2017.

Thus, in sum, the nature and extent of Serrano's cooperation was extensive.

D. <u>Any Injury Suffered, or any Danger or Risk of Injury to the Defendant or His Family Resulting from Assistance (U.S.S.G. § 5K1.1(a)(4))</u>

The Government is not aware of any danger or risk of injury to the defendant. It bears mention that Serrano's cooperation required Serrano to provide information regarding individuals that he was close with, including former Insys employees with whom he was still friendly. Serrano also was the subject of significant publicity at the time of his arrest.

E. Significance and Usefulness of Assistance (U.S.S.G. § 5K1.1(a)(1))

Serrano's cooperation was both highly significant and very useful and contributed substantially to the successful prosecution of doctors who accepted bribes from Insys, as well as other Insys employees who participated in the bribery conspiracy.

Serrano was one of the first former Insys sales representatives to cooperate with the Government's investigation. He provided incriminating information against his former manager at Insys, Jonathan Roper, as well as against four of the five doctors that the Government ultimately indicted in the 18 Cr. 217 matter.

With respect to Roper, Serrano provided additional incriminating information and corroborating evidence that contributed significantly to the Government's filing of superseding charges against Roper in June 2017. This included adding a charge for aggravated identity theft relating to Roper's providing Serrano with instruction about how to forge sign-in sheets for speaker programs, including doing so without the authorization of the individual whose name and signature was being added. Soon after the filing of the superseding charges, Roper began proffering with the Government and he ultimately pled guilty pursuant to a cooperation agreement.

With respect to Freedman, Serrano testified at trial over the course of three trial days. Serrano was Freedman's assigned sales representative for nearly two years, and he provided an in-depth, insider's perspective of Freedman's participation in the Insys bribery conspiracy. Serrano's testimony against Freedman was extraordinarily incriminating. Serrano testified about countless instances of Freedman's speaker programs being purely social affairs involving no education. By way of example, Serrano testified to an instance when Freedman did not even show up at his own speaker program, instead opting to attend a New York Rangers hockey game with Roper that evening. Serrano later had Freedman sign a sign-in sheet reflecting he had been at his own program so that he could be paid by Insys, even though Freedman had not been there. The Government only learned of this incident of Freedman skipping his own speaker program thanks to Serrano, but was able to corroborate the information with credit card records, which showed that Roper had charges on his card at Madison Square Garden (the Rangers' arena) on

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the same evening the speaker program occurred. Serrano testified to explicit conversations he had with Freedman in connection with the bribery scheme, including how he discussed with Freedman that Serrano was hoping Freedman could put new patients on Subsys during the "optin" contest so that Serrano could win the contest, and how Freedman thereafter put more new patients on Subsys, as was corroborated by the prescribing and insurance records. Serrano was the first witness to tell the Government about the fact that Freedman, at times, would tell Serrano he was putting a patient on Subsys before the patient had even come in for their visit, which was corroborated by other evidence presented at trial and constituted particularly devastating evidence of Freedman's guilt.

With respect to Goldstein, while Serrano was his assigned sales representative for only a few months, Serrano still provided significant and useful assistance. This included providing information about the social and, at times, reckless nature of Goldstein's speaker programs. Serrano volunteered that he had done cocaine at Goldstein's speaker programs and taken turns doing lines of cocaine in the bathroom with Goldstein. Serrano disclosed that he had smoked marijuana with Goldstein at Goldstein's office prior to speaker programs. And Serrano provided incriminating information about a strip club outing he had attended with Goldstein, Schlifstein, Roper, and Insys executive Sunrise Lee where Insys paid for private lap dances and drinks for Goldstein and Schlifstein.

With respect to Schlifstein, while Serrano was only his assigned sales representative for only a few months, Serrano provided significant and useful assistance. Serrano was involved in approaching Schlifstein about becoming an Insys speaker and was involved in the nomination process. Serrano provided details about the efforts by Insys to ensure Schlifstein would prescribe large volumes of Subsys in return for selecting Schlifstein as a speaker. Serrano informed the Government of a particularly incriminating set of events in which Insys executive Sunrise Lee had informed Serrano that he should go meet with Schlifstein at Schlifstein's office and that Schlifstein would walk Serrano through which patients he intended to prescribe Subsys to. Serrano then met with Schlifstein at Schlifstein's medical office and Schlifsein looked through his calendar of upcoming appointments and identified specific patients to whom he said he would prescribe Subsys. The Government learned of this incriminating interaction between Serrano and Schlifstein as a result of Serrano's cooperation, and these allegations were included in the Indictment. (See 18 Cr. 217 Indictment, ¶¶ 90-94).

Finally, with respect to Voudouris, Serrano was responsible for recruiting Voudouris as an Insys speaker and was her assigned sales representative for the vast majority of her time as a speaker. Thus, Serrano was able to provide an in-depth, insider's perspective of Voudouris's role in the conspiracy. Serrano provided significant incriminating information against Voudouris. For example, the Government first learned of the September 2, 2014 dinner between Voudouris, Burlakoff, Roper, Serrano, and other Insys executives during which Burlakoff informed Voudouris that Insys wanted Voudouris to prescribe Subsys to one new patient per day and that Voudouris would be allocated speaker programs if she continued prescribing Subsys. (18 Cr. 217 Indictment ¶ 114). The Government was later able to corroborate Serrano's account based on contemporaneous messages and through the accounts of other individuals who had been present at the same dinner. Serrano was also the first witness to inform the Government of follow-up conversations that occurred with Voudouris and Roper where Roper and Serrano

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reinforced the message that Insys expected Voudouris to prescribe more Subsys in light of her having been allocated a substantial number of speaker programs. (18 Cr. 217 Indictment, ¶ 117). Serrano provided a detailed account of the sham nature of Voudouris's sham speaker programs, which rarely involved any education about Subsys. He also provided information regarding Voudouris's role in forging sign-in sheets for her speaker programs, which led to Voudouris being indicted for aggravated identity theft. (18 Cr. 217 Indictment ¶ 36(d), 159-60). Serrano also provided the Government with new information relating to Voudouris writing unnecessary prescriptions of Subsys and stockpiling those prescriptions in her office (18 Cr. 217 Indictment, ¶¶ 122-23), as well as Voudouris's active efforts to assist Serrano win the "opt-in" contest, which included Voudouris providing Serrano and another Insys employee with access to her patient files so that Serrano and the other Insys employee could complete opt-in forms for these patients. (18 Cr. 217 Indictment, ¶¶ 124-29). The information provided by Serrano, along with corroborating evidence, led to Voudouris being charged with a HIPAA violation (18 Cr. 217 Indictment, ¶¶ 165-66), in addition to constituting incriminating evidence of her involvement in the Insys bribery conspiracy.

In addition to the above, Serrano also provided substantial incriminating information against various other Insys executives, managers, and employees. Certain of these former Insys employees ultimately proffered with the Government and entered into non-prosecution agreements, including Sigrid Toulatos, who testified at Freedman's trial.

In sum, Serrano's cooperation in this case was crucial and led to the successful prosecution and convictions of Freedman, Goldstein, Schlifstein, and Voudouris, among others. In the Government's view, he has provided substantial assistance and his cooperation has been fruitful.

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Conclusion

In light of the facts set forth above, and assuming that Serrano continues to comply with the terms of his cooperation agreement, the Government intends to request at sentencing that the Court sentence Serrano in light of the factors set forth in Section 5K1.1 of the Guidelines and, pursuant to Title 18, United States Code, Section 3553(e), without regard to any otherwise applicable mandatory minimum sentence.

Respectfully submitted,

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